

Appl. No. : 10/768,717
Filed : January 30, 2004

REMARKS

Claims 1-17 are currently pending in the application. Claim 1 has been amended for clarification purposes as noted.

Rejections of Claims 1-10 under 35 U.S.C. § 102(b)

Claims 1-10 are rejected under 35 U.S.C. § 102(b) as anticipated by Palestrant (U.S. Patent No. 4,832,055) ("Palestrant"), Chevillion et al (U.S. Patent No. 5,634,942) ("Chevillion"), and Ostrovsky et al (U.S. Patent No. 6,447,530 B1) ("Ostrovsky"). Claim 1 has been amended for clarification to recite an adjustable device deployment system, for implanting an implantable device within an opening in the body comprising: an implantable device, said device being movable between a reduced cross section and an enlarged cross section, said device having a proximal end and a distal end, and wherein said device increases radially in dimension from its proximal end to an apex portion, and then decreases radially in dimension from the apex portion to the distal end; a sheath having a proximal end and a distal end and a lumen adapted to receive the implantable device; a deployment catheter adapted to extend through the sheath having an elongate flexible body with a proximal end and a distal end; and a deployment line adapted to extend through the deployment catheter releasably attached to the implantable device.

Palestrant teaches an inferior vena cava filter with a filter mesh 52 with a flattened mesh configuration shown in Fig. 1 (col. 8, ll. 57-60). Chevillion teaches a blood filter with two substantially conical corollas, the first filtering corolla and the second corolla being head-to-tail (col. 6, ll. 45-48, Fig 7). Ostrovsky teaches an inferior vena cava filter with a generally conical structure (col. 3, l. 10, Fig. 2, 11-13, 15).

In order to anticipate a claim, a prior art reference must identically teach every element of the claim. See M.P.E.P. § 2131. Neither Palestrant, Chevillion, nor Ostrovsky teaches an adjustable device deployment system, said device having a proximal end and a distal end, and wherein said device increases radially in dimension from its proximal end to an apex portion, and then decreases radially in dimension from the apex portion to the distal end. Applicants further submit that a skilled artisan would have no motivation to modify an inferior vena cava filter with the above recited shape characteristics of the present application, and in fact the skilled artisan would find creation of an inferior vena cava filter with the above shape characteristics undesirable.

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Therefore, because of the distinct shape characteristics of the device recited, amended Claim 1 is not anticipated by any of the aforementioned references. We thus request that the Examiner withdraw this rejection. Applicants note that Claims 2-10 depend from Claim 1 and contain all of the limitations thereof in addition to further distinguishing features; thus Applicants submit that these claims are in condition for allowance as well.

Rejection of Claims 11-17 under 35 U.S.C. § 103(a)

The Examiner rejected Claims 11-17 under 35 U.S.C. § 103(a) as being unpatentable over Ostrovsky in view of Brooks et al (U.S. Patent No. 6,346,116 B1) ("Brooks") and Tsugita et al (U.S. Patent No. 5,911,734) ("Tsugita"). The Examiner alleges that Ostrovsky discloses the invention as claimed with the exception of the material of the filter having a membrane and the material of the membrane being ePTFE; Tsugita discloses a filter with a membrane; and that it would have been obvious to have placed a membrane on the filter of Ostrovsky. The Examiner further alleges that this provides an effective means to filter out undesirable particles while allowing blood-flow therethrough, and placing the membrane on the proximal face of the filter as taught by Tsugita will allow the interior of the mesh to be directed upstream to collect debris if introduced in a retrograde orientation. Furthermore, Examiner states it would have been obvious, as in Claim 15, to use ePTFE as the filter material as disclosed in Brooks.

M.P.E.P. § 2143 states the requirements that an Examiner must satisfy in order to establish a case of *prima facie* obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the Applicant's disclosure.

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Applicants contend that the Ostrovsky and Tsugita references are simply not combinable because they are directed to treatment of two very different medical conditions. In particular, a skilled artisan would have no motivation to add the filter membrane (for preventing embolic material from escaping an arterial intervention site during atherectomy/stent placement) of Tsugita (col. 2, ll. 23-27, col. 3, ll. 33-37) to an implantable inferior vena cava filter disclosed by Ostrovsky. Nothing in Ostrovsky teaches or suggests the use of a membrane, let alone utilizing a membrane from an embolic filter with a vena cava filter. In fact, Applicants submit that a skilled artisan would find such a combination, adding a membrane to a vena cava filter, undesirable because the relatively small pore size of a membrane in the low-flow velocity inferior vena cava will tend to induce stasis of blood near the membrane site, and thus thrombosis of the vena cava. This in turn may cause backflow into the distal lower extremity veins, which will in turn cause complications such as massive lower extremity swelling.

Furthermore, Applicants note that there is no teaching or suggestion whatsoever in either Ostrovsky, Tsugita, or Brooks, alone or in combination, for producing the unique combination of features of Claim 11, including, inter alia, an implantable device having a proximal end and a distal end and a plurality of supports extending from the proximal end, the implantable device being movable between a reduced cross section and an enlarged cross section, wherein the implantable device in its enlarged cross section is sized for engaging an inner surface at an atrial appendage, and having a barrier on at least a proximal face of the device. As noted above, Applicants submit that the skilled artisan would find no motivation to combine the filter membrane of Tsugita with the vena cava filter of Ostrovsky. This deficiency is not made up for by Brooks. Moreover, Applicants contend that Examiner has not established that there would be an expectation of success in doing so. Even if the Tsugita filter is delivered retrograde, such that its distal membrane points in a proximal direction, the filter would then be on the proximal side of its delivery catheter, and could not be “distal to the distal end of the deployment catheter” as claimed. Thus, Examiner has failed to establish a *prima facie* case of obviousness under M.P.E.P. § 2143.

In light of the above, Applicants assert that Claim 11 is not obvious in view of the prior art references, and respectfully request that the Examiner withdraw this rejection. Applicants also note that Claims 12-17 depend from claim 11 and contain all of the limitations thereof in

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addition to further distinguishing features; thus Applicants submit that they are in condition for allowance as well.

CONCLUSION

For the reasons presented above, Applicants submit that the present application is in condition for allowance and respectfully request the same. If any issues remain, the Examiner is cordially invited to contact Applicants' representative at the number provided below in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 12/13/05

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